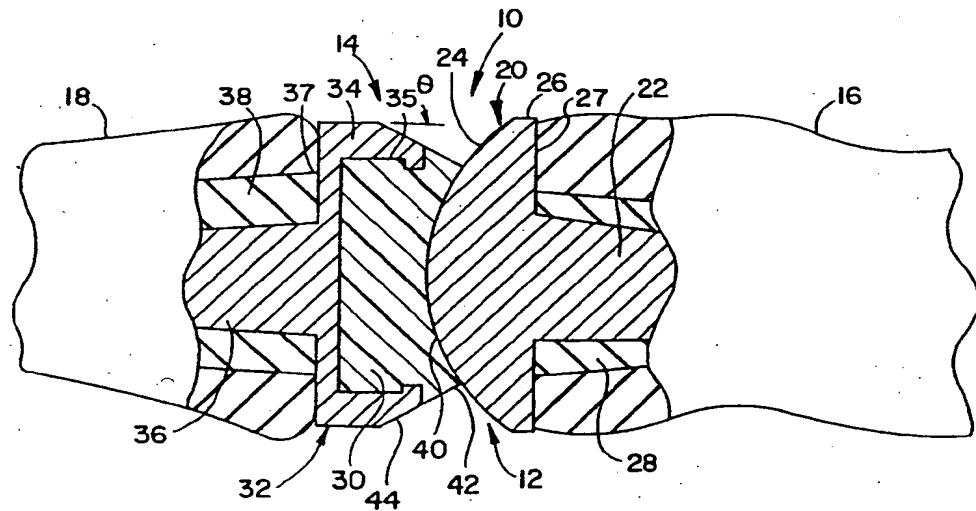




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(54) Title: NON-CONSTRAINED TOTAL JOINT SYSTEM



(57) Abstract

A non-constrained total joint prosthetic replacement device (10) for the metatarso-phalangeal joint. A first component (12) comprises a convex-bearing surface (24) and a rearwardly projecting stem (22) configured to be received in the resected metatarsal bony shaft (16) and a second component (14) includes a concave-bearing surface (40) and a stem (36) configured to be received within the resected phalangeal bony shaft (18). A non-bearing intermediate land (26) offsets the convex-bearing surface (24) of the first component (12) from the stem (22), allowing a full range of anatomical motion notwithstanding the presence of bony growth.

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NON-CONSTRAINED TOTAL JOINT SYSTEM**Field of The Invention**

The present invention relates to non-constrained total joint systems and particularly to prosthetic devices for replacement of metatarso-phalangeal joints.

Background of the Invention

In general, prostheses for replacing defective natural joints between bony shafts are well known. One example of a total joint replacement for the metatarsal phalangeal joint of the foot employs a collared hinge with opposing integral stems, all formed of silicone. To install such a device, an incision is made and the metatarsal and phalangeal bones exposed and resected. Axial channels are formed in the intramedullary canals of the proximal phalanx and metatarsal. The stems are then disposed in the channels, the collars seated against the ends of the bones, and the incision closed. An example of such a silicone hinge replacement is the Sutter Hinged Great Toe Joint Implant, marketed by Sutter Biomedical, Inc.

Non-constrained total joint replacement systems are also known. In the context of the metatarsophalangeal joint, such systems typically include separate metatarsal and phalangeal components configured to be disposed on the ends of the respective resected bony shafts and maintained in place by the soft tissue surrounding the bones.

One type of such non-constrained system employs a metatarsal component including a cap with a rearwardly projecting stem. The stem is received in a channel formed in the intramedullary canal of the metatarsal, and the cap, in effect, covers the end of the metatarsal head, wrapping around the sides of the metatarsal. Resection of the metatarsal in a plurality of planes (i.e., faceting the metatarsal head) is typically required for disposition of the metatarsal cap. The phalangeal component comprises a disc-shaped base with a curved bearing surface and a rearwardly projecting stem. The

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metatarsal component is typically formed of biocompatible metal, and the phalangeal portion formed of polyethylene or of polyethylene backed with metal.

5 Other non-constrained systems employ a metatarsal component comprising a domed head with a rearwardly projecting rectangular cross-section stem. The head includes a convex, part-spherical bearing surface extending to the periphery of the metatarsal component and defining the maximum transverse
10 dimension of the metatarsal component. No portion of the metatarsal component extends transversely beyond the bearing surface. The phalangeal component includes a concave part-spherical bearing surface and a rearwardly projecting stem of generally rectangular cross-section. The radii of the
15 respective bearing surfaces are equal. However, the surface area of the convex bearing surface on the metatarsal component is noticeably larger than the surface area of the concave bearing surface on the phalangeal component. The metatarsal component is formed of a substantially physiologically inert
20 metal, such as orthochrome, and the phalangeal component formed of polyethylene. When implanted, the stems of the metatarsal and phalangeal components are received in respective channels formed in the medullary channels of the bones.

25 Such prior art devices, when implanted, dispose the convex bearing surface immediately and contiguously adjacent to the bone. The present inventors have found that this tends to limit the range of permitted motion in the joint, and
30 renders the system susceptible to bony overgrowth. Such bony overgrowth tends to further limit the permissible range of motion in the joint. Further, various of such prior art systems employ a metatarsal component having a concave part-spherical rear surface. The metatarsal head is craterized to
35 form a recess to receive the metatarsal component so that the edge of the bearing surface abuts metatarsal bone. Such an arrangement is not only particularly susceptible to bony overgrowth, but tends to initiate a periosteal reaction that promotes bony overgrowth. In addition, during extremes of

flexion and extension, the phalangeal component tends to ride off of the metatarsal component onto part of the actual articular surface of the metatarsal head. The polyethylene component thus tends to articulate with already deceased cartilage, often exacerbating a diseased condition and breaking down the actual articular surface of the metatarsal head in the vicinity of the metatarsal component.

Examples of prior art non-constrained systems are 10 the "Total Toe System" marketed by Biomet, Inc. and the system described in U.S. Patent 4,156,296 issued May 29, 1979 to Johnson, et al.

SUMMARY OF THE INVENTION

15 The present invention provides a non-constrained total joint system which provides a full anatomical range of motion, without impingement on or articulation with the actual anatomical structures, and is relatively unsusceptible to bony overgrowth. In general, the system employs first and second, 20 e.g., metatarsal and phalangeal, components. The first component comprises a head and a rearwardly projecting stem configured to be received in the end of the bony shaft. The head includes a convex-bearing surface, and a non-bearing intermediate portion interposed between the stem and the 25 convex-bearing surface, offsetting the convex-bearing surface from the bony shaft end. The second component includes an articulating element and a stem configured to be received in the end of the second cooperating bony shaft. The articulating element includes a concave-bearing surface having 30 a surface area a predetermined amount less than that of the convex surface. The intermediate non-bearing portion provides clearance against impingement and tends to make the joint less susceptible to dysfunction due to bony overgrowth.

35 In accordance with another aspect of the present invention, the side periphery of the articulating element bounding the concave-bearing surface is beveled to a predetermined angle. Such bevel, particularly in cooperation

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with the intermediate portion, permits the full anatomical range of motion without impingement on anatomical structures.

In accordance with another feature of the present
5 invention, intercapsular synovial fluid is employed to moisten and lubricate the bearing surfaces of the prosthesis.

BRIEF DESCRIPTION OF THE DRAWING

A preferred exemplary embodiment of the present
10 invention will hereinafter be described in conjunction with the appended drawings, wherein like designations denote like elements and:

Figure 1 is a partially sectioned front view of a
15 non-constrained joint system in accordance with the present invention installed in respective bony shafts;

Figures 2A, 2B and 2C are front, side, and bottom
20 views of the metatarsal component of Figure 1;

Figure 2D is a partial front view of a second embodiment of a metatarsal component;

25 Figure 2E is a partial sectioned front view of a third embodiment of a metatarsal component;

Figures 3A and 3B are front and front cross-sectional views of the phalangeal insert of the
30 system of Figure 1;

Figure 3C is a detail view of the peripheral bevel of the insert of Figures 3A and 3B;

35 Figures 4A, 4B and 4C are cross-sectional front, side, and bottom views of the phalangeal base unit of the system of Figure 1; and

Figure 4D is a cross-sectional detail view of the periphery of the phalangeal component of Figures 4A, 4B and 4C.

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DETAILED DESCRIPTION OF A PREFERRED EXEMPLARY EMBODIMENT

Referring now to Figure 1, a non-constrained total joint system 10 in accordance with the present invention comprises first and second components, e.g., a metatarsal 10 components 12 and a phalangeal (articulating) component 14, adapted to be received on the ends of respective resected bony shafts, e.g., the metatarsal 16 and phalangeal 18 bones of the big toe. When joint system 10 is implanted in bony shafts 16 and 18, the surrounding soft tissue structure (not shown) 15 maintains component 12 on component 14 in cooperating position.

Metatarsal component 12 comprises a head 20 and a rearwardly projecting stem 22. Head 20 includes a convex bearing surface 24, a non-bearing intermediate portion, e.g., land 26, and a generally flat rear surface 27. Stem 22 is configured to be received in a channel formed in the intramedullary canal 28 of bony shaft 16, with rear surface 27 abutting the resected end of metatarsal bony shaft 16. Non-bearing intermediate portion, e.g., land 26, offsets convex bearing surface 24 from the end of bony shaft 16 by a predetermined amount. Component 12 is suitably formed as an integral unit of biocompatible metal, e.g., cobalt chrome, and will be more fully described in conjunction with Figures 2A-30 2C.

Phalangeal component 14 preferably comprises an intermediate bearing insert 30 formed of biocompatible plastic, e.g., ultra high molecular weight polyethylene, and 35 a base unit 32 formed of biocompatible metal, e.g., titanium. As will be more specifically described in connection with Figures 3A-3C, insert 30 is suitably relatively thin, including a generally cylindrical rear portion and a frustroconical forward section with a concave bearing surface 40 in

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the front face thereof configured for cooperation with convex bearing surface 24. A beveled forward side periphery 42 is presented in the vicinity of surface 40. Concave surface 40 is of a surface area smaller, by a predetermined amount, than 5 the surface area of convex surface 24. Base unit 32 comprises a receptacle portion 34 and a rearwardly projecting stem 36. Receptacle portion 34 includes a forward-opening lipped chamber 35, a generally circular rear surface 37 and a beveled forward peripheral side surface 44. Insert 30 is configured 10 to be received and secured (press fit) in receptacle 34, with concave surface 40 outward. The forward side periphery 42 of insert 30 and forward side periphery 44 of base receptacle 32 are each beveled to a predetermined angle θ_1 .

15 Stem 36 extends rearwardly from rear surface 37, and is configured to be received in a channel formed in the intramedullary canal 38 of phalanx 18 with rear surface 37 of base unit 34 abutting the resected end of bony shaft 18. When 20 joint system 10 is implanted in bony shafts 16 and 18, the surrounding soft tissue structure (not shown) causes concave bearing surface 40 to ride on convex bearing surface 24.

Joint system 10 provides the full anatomical range of motion, e.g., upwards of 60° in the sagittal plane, and 25 maintains an approximation of the true anatomical center of motion, not only through flexion and extension of the toe, but also through pronation and supination encountered by the great toe during walking. Use of an intermediate portion, e.g., land 26, to offset convex surface 24 from the end of 30 bone 16 facilitates use of a convex bearing surface 24 having a relatively large radius of curvature, i.e., relatively flat (approximating that of the anatomic articulating surface, while, at the same time, providing sufficient clearance for articulating component 14 as against bony shaft 16 and 35 possible bony overgrowth. Full anatomical range of motion and approximation of the true anatomical center of motion, without impinging on any anatomical structure, is provided for by using, particularly in conjunction with the offset provided by land 26, an articulating component 14 with a concave surface

40 having a relatively small surface area, and having a beveled forward side periphery. The relative dimensions of bearing surfaces 24 and 40 are such that with the joint at the upper range of maximum anatomical flexion, as defined by the 5 surrounding soft tissue structure, concave bearing surface 40 is still substantially riding upon the convex bearing surface 24, or overhangs the bearing surface only by a predetermined limited amount, as will be explained. The bevel of side peripheral surfaces 42 and 44 ensures that there is no 10 impingement upon the metatarsal anatomical structure, or any bony overgrowth or soft tissue ingrowth that may occur. It is desirable to make bevel angle θ_1 as large as possible, e.g., on the order of 20° to 35°, and preferably approximately 30°, without losing stability of contact between bearing surfaces, 15 i.e., without decreasing the diameter of the concave bearing surface to below a predetermined minimum, e.g., in the range of from 5 to 15 millimeters (mm), and preferably 11 to 13 mm.

Joint system 10 can be installed employing a 20 relatively simple procedure: an incision is made over the joint; bones 16 and 18 are exposed; a single straight planar resection is effected at the end of each bone, thereby removing the anatomical joint; axial channels are formed in intramedullary canals 28 and 38; stems 22 and 26 of components 25 12 and 14 are pressed into the channels (with fixative as appropriate) until the rear surfaces 27 and 37 of the components abut against the resected ends of bones 16 and 18, respectively. The dimensions of components 12 and 14 are such that resection of a relatively small amount of bone material 30 is required and the integrity of the soft tissue structures in the vicinity of the joint important for stability of the great toe, and in particular the flexor tendon group, can therefore be preserved. As noted above, the use of land 26 to offset convex bearing surface 24 from the end of bone 16 facilitates 35 the use of a larger radius of curvature than would otherwise be possible, while still providing adequate clearance over anatomical structures and any bony overgrowth. This results in metatarsal head 20 having an overall height less than would otherwise be required. Further, the use of relatively thin

polyethylene bearing insert 30 maintained within a shallow, but strong, metal base 32 provides a particularly stable, axially thin phalangeal component. In situ, insert 30 is largely encapsulated by metal; the bulk of insert 30 is 5 retained within metal receptacle 32 and concave surface 40 is faced by metal bearing surface 24. There is no polyethylene-on-bone interface, or articulation. Thus, phalangeal component 14 can be thinner, yet better resist fragmentation and wear than a unitary polyethylene phalangeal component. 10 Moreover, the stability and longevity of joint system 10 are substantially improved; metal-on-metal and bone-on-polyethylene contacts, which are subject to abrasive wear, are avoided. Use of metal stems 22 and 36, and flat metal rear surfaces 27 and 37, also promotes stability of the implant and 15 bonding of components 12 and 14 to bones 16 and 18.

It is desirable that the respective diameters of rear surfaces 27 and 37 approximate, preferably by being at least equal to, the diameter of the corresponding resected 20 bone end. The present inventors have found that the metatarso-phalangeal joint of the large majority of adult humans can be accommodated using combinations of two sizes (small and large) of metatarsal 12 and phalangeal 14 components. The small and large size phalangeal components 14 25 are designed to cooperate with both the small and large metatarsal components 12.

Referring now to Figures 1, 2A, 2B and 2C, metatarsal component 12 will be more specifically described. 30 As previously noted, component 12 comprises head 20 and stem 22. Head 20 includes convex bearing surface 24 and an intermediate non-bearing portion, e.g., land 26. Convex bearing surface 24 is suitably in the form of the surface of a part sphere or part spheroid or ellipsoid having a major 35 radius of curvature R_1 , suitably in the range of from approximately 7 to 17 mm, preferably $9.53 \pm .05$ mm for a small, or $12.70 \pm .5$ mm for a large, component. Bearing surface 24 abuts and is contiguous with the intermediate non-bearing surface (land 26) in the embodiment of Figures 1, 2A, 2B and

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2C. Land 26 is suitably cylindrical, with a diameter D_1 (Figure 2C) and axial height D_2 (Figure 2A), and defines a generally circular flat rear surface 27. Diameter D_1 suitably ranges from approximately 13 to 25 mm, preferably either 5 approximately 15.88 mm for a small, or 18.80 mm for a large, component. Height D_2 suitably ranges from approximately .5 to 1.5 mm, preferably either approximately .83 mm for a small, or .91 mm for a large, component. The overall axial height D_3 of metatarsal head 20 is suitably on the order of 3 to 8 mm, and 10 preferably approximately 5.08 mm.

Stem 22 projects axially from rear surface 27 to a predetermined distance D_4 , of on the order of 16 mm, preferably approximately 15.75 mm for both small and large component 12. 15 Stem 22 is preferably generally centered on rear surface 27, and exhibits a rectangular cross-section that decreases with distance from the juncture with rear surface 27. More specifically, the projection of stem 22 into the frontal plane (Figure 2A) is a quadrilateral formed by respective opposing 20 sides 22A and 22B, an end 22C and a juncture 22D with surface 27. Side 22A is disposed parallel to the central axis of component 12, i.e., perpendicular to rear surface 27, offset from the centerline by a predetermined distance D_5 . Distance D_5 suitably ranges from approximately 3 to 4 mm, preferably 25 approximately 3.18 mm for a small, or 3.81 mm for a large, component. Opposing side 22B is disposed at a predetermined angle θ_2 , e.g., on the order of 10° from the central axis. Stem 22 is suitably of a predetermined width D_6 at juncture 22D with rear surface 27. Width D_6 suitably ranges from 30 approximately 5 mm to 9 mm, preferably approximately 6.35 mm for a small, or 7.82 mm for a large, component. End surface 22C of stem 22 is suitably parallel to rear surface 27, and is of predetermined width D_7 , suitably in the range of from approximately 2.5 to 5.5 mm, and preferably approximately 35 3.58 mm for a small, or approximately 4.27 mm for a large, component.

The projection of stem 27 in the coronal plane (Figure 2B) is a generally wedge-shaped quadrilateral formed

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by respective opposing sides 22E and 22F and 22C and a juncture 22G with rear surface 27. Sides 22E and 22F are each tapered at a predetermined angle θ_3 , suitably on the order of 5° and preferably approximately 5.3°, from the axis of 5 component 12. Stem 22 manifests a predetermined height D_8 at the juncture with rear surface 27, and tapers to a lesser height D_9 at end 22C. Height D_8 suitably ranges from approximately 5 to 9 mm, and preferably either approximately 5.23 mm for a small, or approximately 8.80 mm for a large, 10 component. Height D_9 suitably ranges from approximately 2.25 to 3.5 mm, preferably approximately 2.54 mm for a small, and 3.05 mm for a large, component.

Referring now to Figures 1 and 3A, 3B and 3C, insert 15 30 will be more particularly described. Insert 30 is suitably formed as an integral unit of a biocompatible plastic such as ultra high molecular weight polyethylene, and includes the following respective contiguous, coaxially aligned sections: rear section 50; intermediate section 52; and forward section 20 54. Rear section 50 is generally in the form of a cylinder having a diameter D_{10} , with a substantially flat rear surface 56, and chamfered rear edges 58. Edges 58 are suitably chamfered to approximately 45° to a distance of approximately .64 mm, to facilitate insertion of insert 30 into lipped 25 chamber 35, as will be explained. Diameter D_{10} is maintained to relatively close tolerance, and suitably ranges from approximately 8 to 15 mm, preferably approximately $11.56 \pm .03$ mm for a small, or $12.5 \pm .03$ mm for a large, component.

30 Intermediate section 52 is also cylindrical, with a predetermined diameter D_{11} , less than diameter D_{10} of first section 50, and predetermined axial height D_{12} . Diameter D_{11} suitably ranges from approximately 11 to 13.5 mm, preferably 11.66 mm for a small unit, or 13.08 mm for a large unit. 35 Axial height D_{12} is maintained to close tolerance, suitably .81 mm -0, +.13 mm for both large and small components.

Forward section 54 suitably includes a cylindrical land 54A merging with an integral frustro-conical section 54B,

which presents beveled forward peripheral side 42 of insert 30. As previously noted, periphery 42 is beveled to a predetermined angle θ_1 , preferably on the order of 30° . Land 54A is suitably of a predetermined diameter D_{13} , greater than 5 diameter D_{10} of first section 50, and height D_{14} (Figure 3C). Diameter D_{13} suitably ranges from approximately 10 to 16 mm, preferably approximately 13.11 mm for a small unit, or 14.15 mm for a large unit. Height D_{14} is suitably on the order of .4 mm, preferably .38 mm for both large and small 10 components. Forward section 54 manifests a predetermined aggregate height D_{15} . Height D_{15} suitably ranges from approximately 1 to 2 mm, preferably 1.63 mm for a small unit, or 1.47 mm for a large unit.

15 As best seen in Figures 3B and 3C, concave bearing surface 40 is formed in the face of frustro-conical section 54, centrally disposed and bounded by a thin concentric peripheral land 60 of a predetermined width D_{16} . Width D_{16} is suitably on the order of .5 mm, and preferably .51 mm, for 20 both small and large units.

Surface 40 is configured to cooperate with convex bearing surface 24, and is preferably in the form of a portion of the interior of a hollow sphere having a predetermined 25 radius R_2 , suitably approximating, and preferably equal to, the major radius R_1 of convex surface 24, with a center of curvature disposed on the central axis of insert 30 at a distance D_{17} axially forward of the front surface of forward section 54. Distance D_{17} suitably ranges from approximately 30 7.5 to 11.5 mm, preferably approximately 7.90 mm for a small unit, and 11.23 mm for a large unit. Thus, surface 40 forms a recess in the face of section 54 extending axially inward to a predetermined depth D_{18} , suitably ranging from approximately 1 to 2 mm, preferably 1.63 mm for a small unit, and 1.47 mm 35 for a large unit. Rear section 50, intermediate section 52, and land 54A cooperate to form a peripheral recess in insert 30, of a depth D_{19} (Figure 3C) equal to the difference between diameters D_{10} and D_{11} , suitably on the order of .05 mm, and preferably .06 mm.

Referring now to Figures 1, 4A, 4B, 4C and 4D, base unit 30 comprises, as noted above, receptacle portion 34, including forward opening chamber 35 and rear surface 37, and stem 36. Receptacle portion 34 includes a generally cylindrical rear portion 34A and an integral frustro-conical forward portion 34B. Rear portion 34A is of a predetermined outer diameter D_{20} (Figure 4C), and presents a generally flat, circular rear surface 37. Diameter D_{20} is suitably somewhat smaller than diameter D_1 of metatarsal head 20, generally corresponding to the diameter of the resected end of bone 18, and suitably ranges from approximately 15 to 17.5 mm, preferably approximately 15.24 mm for a small unit, and 17.27 mm for a large unit. Forward portion 34B presents beveled forward peripheral side portion 44, which is chamfered to a predetermined angle θ_3 , preferably substantially equal to the chamfer angle of insert periphery 42, i.e., approximately 30°, and culminating at a forward face 39 of receptacle 34. Forward portion 34 manifests a predetermined axial height D_{32} suitably ranging from approximately 1.25 to 2.5 mm, preferably 1.47 mm for a small unit, and 2.2 mm for a large unit. Receptacle 34 manifests a predetermined aggregate axial height of on the order of 5 mm, preferably 4.90 mm for both small and large units. Chamber 35 is disposed centrally in face 39, generally cylindrical in shape, of a predetermined diameter D_{21} , and extending inwardly to a predetermined depth D_{22} . Diameter D_{21} generally corresponds to the diameter D_{10} of rear section 50 of insert 30, suitably ranging from approximately 11.5 to 13 mm, preferably 11.88 ± 3 mm for a small unit, and 12.62 ± 3 mm for a large unit. Depth D_{22} generally corresponds to the aggregate height D_{23} (Figure 3A) of sections 50 and 52 of insert 30. Depths D_{22} and D_{23} are preferably equal and maintained to close tolerance, suitably 3.63 mm -0, +.13 mm.

A lip 62 is formed about the mouth of chamber 35 projecting radially inward a predetermined distance D_{24} (Figure 4D), suitably on the order of .1 mm, preferably .13 mm, such that the mouth of chamber 30 presents a circular opening of a predetermined diameter D_{25} slightly greater than diameter D_{11} of intermediate portion 52 of insert 30, but smaller than

diameter D_{10} of rear section 50. Diameter D_{25} suitably ranges from approximately 11 to 12.5 mm, preferably $11.43 \pm .03$ mm for a small unit, and 12.37 ± 0.3 mm for a large unit. The front face 39 of receptacle 34 is thus annular, with an inner 5 diameter D_{25} defined by lip 62, and an outer diameter D_{28} (Figure 4B) defined by the edge of chamfered side 44. Outer diameter D_{28} suitably ranges from approximately 13 to 15 mm, preferably approximately 13.45 mm for a small unit and 14.73 mm for a large unit.

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Lip 22 is of a predetermined axial height D_{26} , suitably .76 mm +0, -.13 mm, closely corresponding to (slightly less than) the axial height D_{12} of intermediate section 52 of insert 30, i.e., of the peripheral recess about 15 insert 30. Lip 22 is employed to retain insert 30 in chamber 35.

Insert 30 snap-fits into chamber 35 with concave surface 40 outward and forward section 54 maintained 20 exteriorly of the chamber. Chamfered edges 58 of insert 30 cause rear surface 56 to be of a slightly lesser diameter than diameter D_{25} of the mouth of chamber 35, facilitating insertion of rear section 50 into chamber 35. Insert 30 is sufficiently resilient to permit rear section 50 to compress to pass lip 25 62. Lip 62 ultimately engages the peripheral recess in insert 30 at intermediate section 52. Thus, when insert 30 is fully received in chamber 35, rear surface 56 of insert 30 abuts the rear interior surface of chamber 35, and the rear surface of insert forward section 54 abuts receptacle front surface 39, 30 overlying lip 62.

Stem 36 extends axially rearward from rear surface 37 of receptacle 34 a predetermined distance D_{36} (Figure 4B) suitably ranging from approximately 11 to 13 mm, preferably 35 approximately 11.07 mm for a small, and 12.7 mm for a large, component. Stem 36 is preferably generally centered on rear surface 37 and exhibits a rectangular cross-section that decreases with distance from the juncture with rear surface 27. The projection of stem 36 in the frontal plane (Figure

4A) is a generally wedge-shaped quadrilateral formed by respective opposing sides 36A and 36B, and end 36C and a juncture 36D with rear surface 37. Juncture 36D is of a predetermined width D_{38} suitably ranging from approximately 5 to 7 mm, preferably approximately 5.59 mm for a small, and 6.60 mm for a large, component. Sides 36A and 36B each taper inwardly by a predetermined angle θ_6 , preferably on the order of 3.5° for both large and small components such that the projection of end 36C is of a lesser predetermined width D_{40} , suitably ranging from approximately 4 to 5.5 mm, preferably approximately 4.22 mm for a small, and 5.08 mm for a large, component.

The projection of stem 36 in the coronal plane 15 (Figure 4B) is likewise a generally wedge-shaped quadrilateral, formed of respective opposing sides 36E and 36F, end 36C, and a juncture 36G with rear surface 37. Juncture 36G presents a predetermined width D_{42} , suitably ranging from approximately 3.5 to 5 mm, preferably approximately 3.61 mm for a small, and 4.57 mm for a large, component. Sides 36E and 36F each taper inwardly by a predetermined angle θ_8 , suitably ranging from 2.5 to 4°, preferably approximately 2.8° for a small, and 3.4° for a large, component. The projection of end 36C presents a 25 predetermined width D_{44} , suitably ranging from approximately 2 to 3.5 mm, preferably approximately 2.54 mm for a small, and 3.05 mm for a large, component.

The various portions of the exterior of metatarsal 30 component 12 and phalangeal base unit 32 are treated to selectively promote, or inhibit, bony ingrowth. Specifically, the surfaces of stems 22 and rear surfaces 27 and 37 are textured (roughened), suitably employing a 5-micron grit blast, to promote bony ingrowth to enhance bonding of the 35 components to the bones. In contradistinction, land 26 of metatarsal component 12 and the side surfaces of phalangeal receptacle 34 are polished (in the manner of bearing surface 24) to inhibit bony overgrowth.

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In some instances, it is desirable to include provisions to facilitate lubrication between bearing surfaces 24 and 40 by natural intercapsular synovial fluid, to reduce friction between, and concomitant wear on, the bearing surfaces. Referring to Figure 2D, this is accomplished by including a frustro-conical portion as part of the intermediate portion of metatarsal head 20, disposed to extend transversely beyond bearing surface 24. More specifically, a cylindrical land 26A merges with a frustro-conical section 26B, which in turn merges with bearing surface 24. Frustro-conical section 26B is suitably disposed at a predetermined angle θ_{10} , and presents an axial height on the order of 0.5 mm, preferably approximately 0.40 mm for both small and large components. Angle θ_{10} suitably approximates, but is slightly less than, the tangent to bearing surface 24 at the juncture with frustro-conical section 26B.

With reference to Figures 1 and 2D, during extremes of flexion and extension, the edge of phalangeal component 14 overhangs bearing surface 24 by a predetermined limited amount corresponding to the transverse width of frustro-conical section 26B. Since frustro-conical section 26B is disposed transversely beyond bearing surface 24 and manifests an angle less than the tangent to bearing surface 24, concave bearing surface 40 is separated from frustro-conical section 26B by a small space, permitting the introduction of intercapsular synovial fluid under surface 40. If desired, a shallow channel (not shown) can be formed in concave bearing surface 40 to further facilitate lubrication. The relative dimensions of the components are offset such that even in the extremes of flexion and extension, concave bearing surface 40 never extends transversely beyond land 26A, and impingement with anatomical structures and possibly bony overgrowth is avoided.

As previously mentioned, phalangeal base unit 32 is formed of titanium. The use of titanium is particularly advantageous in that titanium is extremely biocompatible and amenable to texturing, e.g., by grit blasting, to promote bony ingrowth to hold the component securely in place in bone 18.

For those reasons, it would also be desirable to form metatarsal component 20 of titanium. However, titanium does not provide an optimum bearing surface for polyethylene. Accordingly, bearing surface 24 (and hence the entirety of 5 metatarsal head 20 when a unitary component) is formed of cobalt chrome. It is also desirable to employ, in some situations, stems of varying configurations, e.g., longer, wider, narrower, at angles varying from the norm, etc. Accordingly, components 12 and 14 can be made to engage stem 10 sleeves of varying configuration to accommodate varying situations. Referring to Figure 2E, a metatarsal head 20, formed of cobalt chrome, includes a short tang 70. Tang 70 is slightly tapered, and is received in a conforming channel in the end of a stem sleeve 72, suitably formed of textured 15 titanium, manifesting a desired configuration. The channel in stem sleeve 72 has an angle slightly shallower than the taper of tang 70, so that a secure press fit is effected between head 20 and sleeve 72.

20 It will be understood that the above description is of preferred exemplary embodiments of the present invention, and the invention is not limited to the specific forms shown. Modifications may be made in the design and arrangement of the elements within the scope of the invention, as expressed in 25 the claims.

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Claims

1. A non-constrained, total joint system for effecting an articulation between first and second adjacent resected bony shafts, the system comprising:
 - 5 A first component, including:
 - a first stem configured to be received in the end of said first bony shaft;
 - a convex, semi-spherical bearing surface, said convex bearing surface extending no more than 180°;
 - 10 a non-bearing intermediate portion interposed between said first stem and said convex bearing surface, offsetting said convex bearing surface from said bony shaft end; and
 - A second component, comprising:
 - 15 a second stem configured to be received in the end of the second bony shaft;
 - an articulating element including a concave, semi-spherical bearing surface conforming to said convex surface and being of an area significantly less than the area of said convex bearing surface; and
 - 20 means for fixedly attaching said articulating element to said second stem.
2. The system of Claim 1 wherein said means for fixedly attaching said concave bearing surface to said second stem comprises a base formed of a non-plastic biocompatible material integral with said second stem, and including a recessed portion configured to receive at least a portion of said articulating element therewithin; and means for securing said articulating element in said recess.
 - 25
 - 30
3. The system of Claim 2 wherein said articulating element is formed of biocompatible plastic.
 - 35
4. The system of Claim 3 wherein said articulating element is formed of ultrahigh molecular weight polyethylene.

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5. The system of Claim 1 wherein said articulating element includes a peripheral portion transversely bounding said concave bearing surface, the transverse dimensions of said peripheral portion increasing as a function of
5 distance from said concave bearing surface.

6. The system of Claim 5 wherein said peripheral portion is frustro-conical.

10 7. The system of Claim 1 wherein said articulating element comprises a generally cylindrical body having first and second opposing surfaces, said concave bearing surface being formed in said first opposing surface.

15 8. A non-constrained total joint system for effecting an articulation between first and second adjacent resected bony shafts, the system comprising:

A first component formed of non-plastic biocompatible material and including:

20 a first stem configured to be received in the end of said first said bony shaft;

a convex, semi-spherical bearing surface, said convex bearing surface extending up to 180°; and means for fixedly attaching said convex bearing surface transversely to said first bony shaft;

25 A second component, including:

a second stem adapted to be received in the end of said second bony shaft;

a receptacle portion attached to said second stem;
30 and

An intermediate insert formed of a biocompatible plastic, fixedly disposed in said receptacle portion, said insert including a concave, semi-spherical bearing surface conforming to said convex bearing surface and of an area significantly less than the area of said convex bearing
35 surface.

9. The system of Claim 8 wherein said intermediate insert is formed of ultrahigh molecular weight polyethylene.

10. The system of Claim 8 wherein said first component is formed of cobalt chrome.
11. The system of Claim 8 wherein said second component is 5 formed of titanium.
12. The system of Claim 8 wherein said intermediate insert includes a generally cylindrical body with first and second opposing end surfaces, said concave bearing 10 surface being formed in said first end surface;
Said body including a peripheral portion adjacent to said first end surface, said peripheral portion increasing in diameter as a function of axial distance from said first end surface.
15
13. The system of Claim 8 including means for effecting a snap fitting of said intermediate insert in said receptacle portion.
- 20 14. The system of Claim 8 wherein said first and second stems have a generally rectangular cross-section.
15. The system of Claim 12 wherein the surface of said peripheral portion is at an angle within the range of 20° 25 to 35° relative to said body.
16. The system of Claim 15 wherein said receptacle portion includes an outer peripheral portion having an angle corresponding to the angle of said intermediate insert 30 peripheral portion.
17. The system of Claim 8 wherein said means for fixedly attaching said convex bearing surface transversely to said shaft comprises a non-bearing intermediate portion 35 interposed between said second stem and said convex bearing surface.
18. The system of Claim 17 wherein said non-bearing intermediate portion comprises a cylindrical portion

adjacent to said second stem, and a frustro-conical portion adjacent to said convex bearing surface.

19. The system of Claim 18 wherein said frustro-conical portion manifests an angle that is no greater than the tangent to said convex bearing surface at the juncture of said convex bearing surface and said frustro-conical portion.

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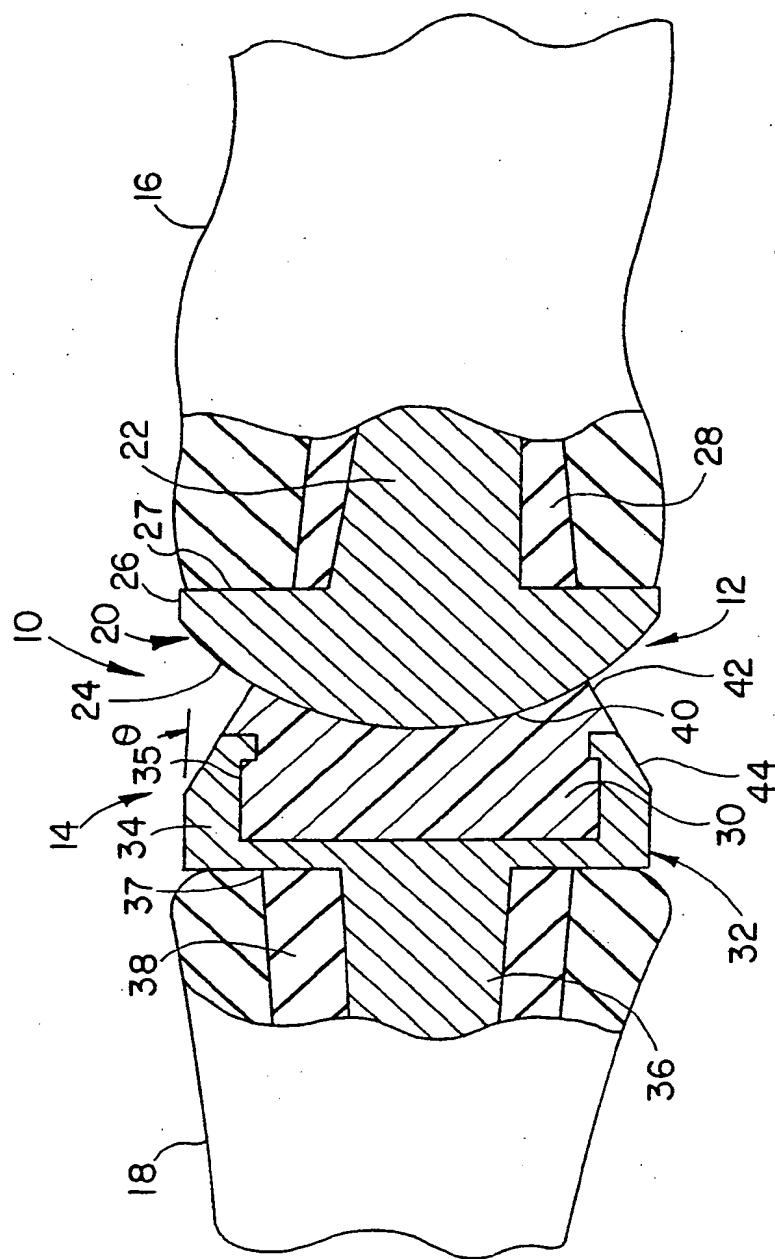


FIG. I

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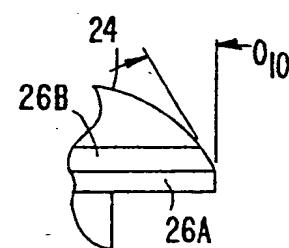
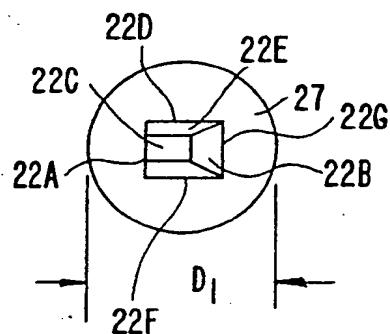
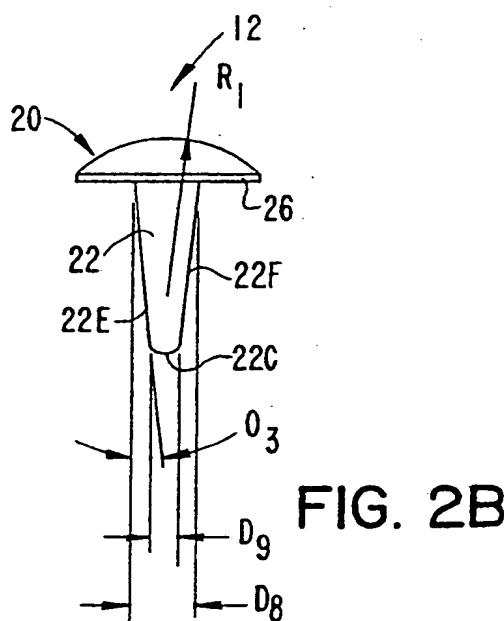
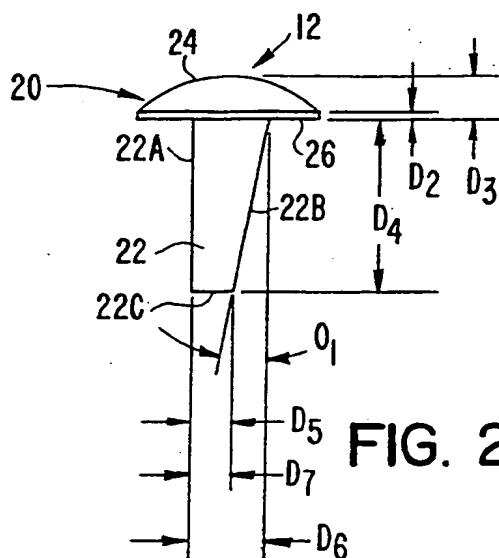
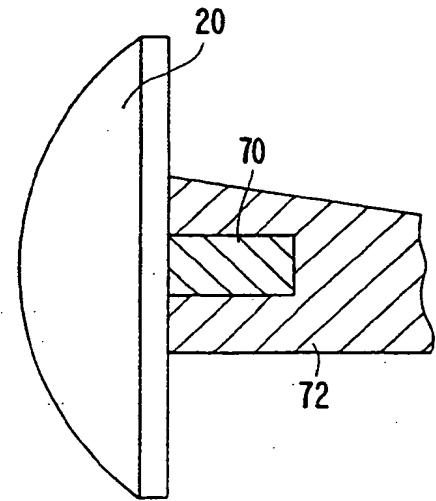
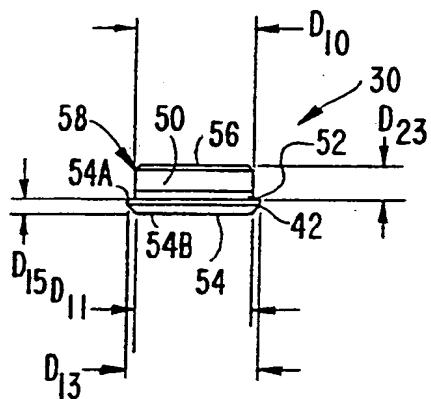
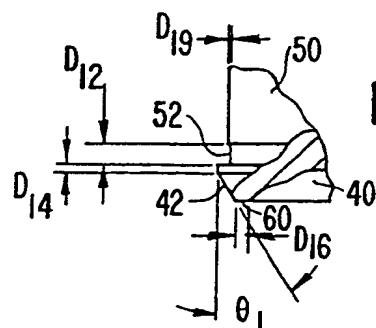
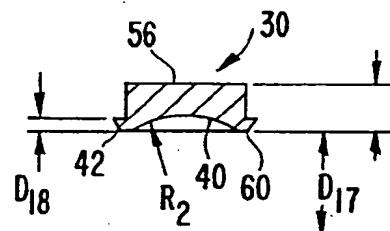
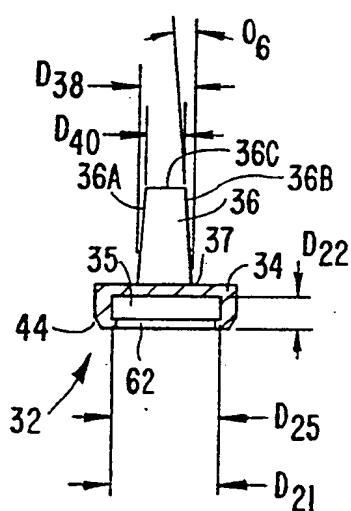
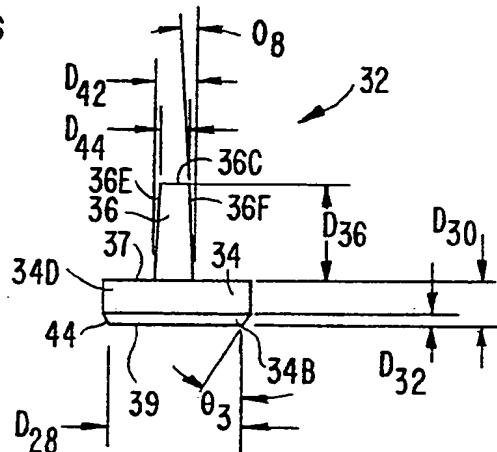
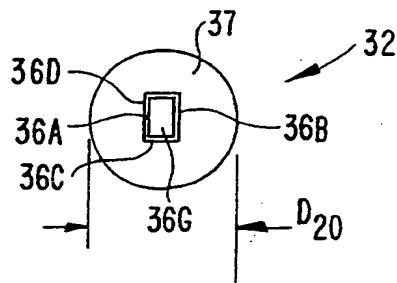
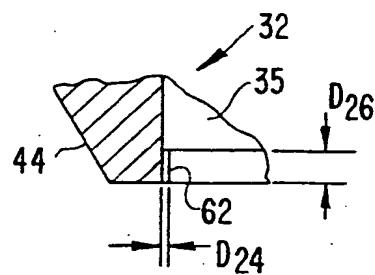


FIG. 2C



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FIG. 3A**FIG. 3B****FIG. 3C****FIG. 4A****FIG. 4B****FIG. 4C****FIG. 4D**

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/05430

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61F 2/42

US CL : 623/21

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/18,19,20

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US.A, 3,889,300 (Smith) 17 June 1975 see entire document.	1-17
Y	US.A, 4,021,864 (Waugh) 10 May 1977 see entire document.	1-4,7-11,13 14 and 17
Y	US.A, 4,470,158 (Pappas et al.) 11 September 1984 see figures 1-28, column 5 lines 48-68, all of columns 6-9 and column 10, lines 1-31.	1-17
Y	WO,A, WO89/06946 (Berggren et al.) 10 August 1989. See page 4, lines 12-35 and page 5, lines 1-23.	11

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance		
E earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
O document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

07 AUGUST 1992

Date of mailing of the international search report

13 NUV 1992

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